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Informed Consent Form

Project Title: Preventing Alcohol Exposed Pregnancy among Urban Native Young Women: Mobile CHOICES
Principal Investigator: Carol E. Kaufman and Michelle Sarche (MPI)
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Study Title: Preventing Alcohol Exposed Pregnancy among Urban Native Young Women: Mobile CHOICES

You are being asked to be in a research study. This form provides you with information about the study. Please read the information below. If you have questions about anything you don't understand you can contact the study investigators before deciding whether or not to take part. Their information is provided at the end.

Why is this study being done?

This study plans to learn if using the study cell phone app can help prevent alcohol exposed pregnancy.

You are being asked to be in this research study because you are a Native American young woman, 16-20 years old, who is not pregnant or breastfeeding at this time. You also live in a city that is at least 50,000 in population, but not on tribal land.

Other people in this study

Up to 720 people around the country will be in the study.

What happens if I join this study?

If you join the study, you will first fill out an online survey. The survey will last about 30 minutes and your answers will be recorded. You will then be asked to download the study app to use on a smartphone. You will be asked to complete the sessions in the app within 1 month. This should take about 4 hours total. You will be randomly assigned to one of two topics in the app. One topic includes information about alcohol, birth control, and sexually transmitted infections. The other topic includes information about life skills. The surveys you take will have questions about both topics.

We want to learn how using the app affects what you know and do about these topics, to learn that, we will ask you to fill out three more surveys over about 12 months. We will ask you to fill out surveys at 1 month, 6 months, and 12 months after you fill out the first survey. Each survey will take about 45 minutes. In total, your participation in the study will last about 12 months.

We may reach out to you asking to participate in phone or video interviews. The interview will last approximately one hour. The interview will be conducted by telephone and recorded. We want to learn about the impacts of the COVID pandemic on the topics listed above.

We may ask you to follow our page on social media platforms like Instagram, share our recruitment post on your social media platforms, and tag us in that post. We will offer a small compensation if you complete this task. This is completely voluntary and the recruitment post does not require you to disclose any personal health information.

What are the possible discomforts or risks?
Discomforts you may experience while in this study include minor emotional discomfort if the topics of alcohol use, birth control, and sexual activity are difficult for you.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

You will be assigned to a study treatment by chance, and the study treatment you receive may prove to be less effective or to have more discomforts than the other study treatment.

We may ask you to share and tag our recruitment post on your Instagram. This may disclose to others that you are a participant in the study. Tagging and sharing our recruitment post is completely voluntary and does not require you to disclose any personal health information.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about if a phone app can help prevent alcohol exposed pregnancies. You may learn new things about alcohol, birth control, sexual activity, or life skills. You will know you helped test an app designed for Native young women to improve the health that could help others like you.

This study is not designed to treat any illness or to improve your health.

Who is paying for this study?

This research is being paid for by the National Institute of Alcohol Abuse and Alcoholism (NIAAA), a part of the National Institutes of Health (NIH).

Will I be paid for being in the study?

You will be paid for being in this study. You will be paid $25 for the first survey, $35 for the second, $40 for the third, and $50 for the fourth survey. You will also be paid $10 for downloading the app and $10 for completing the app sessions. So we can stay in touch with you during the project, we will send you an email or text every couple of months. If you reply, we will send you $10. If you refer friends to our study, we will pay you $5 up to 3 times when you refer someone who is eligible and enrolls. In total, over 12 months, you could get up to $215. If you leave the study early, or if we have to take you out of the study, you will be paid only for the parts you have completed. We may ask you to follow us on our Instagram, share our recruitment post and tag us on that post. You will receive $5 for completing this task. This is completely voluntary and does not require you to disclose any personal health information.

If you are asked to participate in a phone interview and you agree, you will be paid $40 in an Amazon gift card for each interview.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study. The study requires engagement with a cell phone app. Depending on your data plan, you may have to pay for minutes or data you use. The e-gift cards you receive for downloading and completing the app can help to offset those costs.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study researcher may decide to stop your participation without your permission if she thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

Who do I call if I have questions?

The researchers carrying out this study are Carol Kaufman and Michelle Sarche. If you have questions, concerns, or complaints later, you may call Dr. Kaufman at 303-724-1464 or Dr. Sarche at 303-724-1460.

You may have questions about your rights as someone in this study. You can call Dr. Kaufman or Dr. Sarche with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- Centers for American Indian and Alaska Native Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Carol Kaufman or Michelle Sarche
Centers for American Indian and Alaska Native Health
University of Colorado – Anschutz Medical Campus
MS F500
13055 East 17th Avenue
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study researchers and the rest of the study team.
- NIAAA. who is the sponsor paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

To those connected with the research,

- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or

- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make some of the following health information about you collected in this study available to:

- NIAAA, the sponsor of this study
- The data safety and monitoring board, a group of 3 researchers who make sure our team is keeping your data safe.

Information about you that will be seen, collected, used and disclosed in this study:

- Demographic Information (first name, age, birth month and year, sex, ethnicity or race)
- Research records from the survey
- Other (please specify): Pregnancy status, alcohol or substance use, contraceptive use status

What happens to data collected in this study?

Scientists at the University involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, the University involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

We need to do a quick knowledge check to make sure you understand some important parts about what being in our study means for you.

Please answer **true or false** to the following statements:

1. My participation in this study is voluntary.

- ○ True
- ○ False

2. Once I sign up to be in the study I have to stay in the study the whole time.

- ○ True
- ○ False

3. I can skip a question if I do not want to answer it.

- ○ True
- ○ False

Agreement to be in this study and use my data

I have read about the study. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary.
I choose to be in this study.

- ○ I choose to be in the study (if selected, go to signature section, below)
- ○ I do not want to participate (if selected, participant is thanked and consent process ends)

Signature section

Thank you for be willing to participate! Please sign (with your finger, a stylus, or mouse) in the space below to show you consent electronically to be in this study

Signature block

Today's date:

Would you like to receive a copy of the signed consent form? You can also take a screen shot or a video screen recording for your records.

Please know it may take up to 2 weeks to receive the signed form.

- o No, I don't need a copy of the signed consent form.
- o Yes, please send a PDF of the signed consent to the email address I provided.
- o Yes, please send a hard copy of the signed consent to my mailing address

Thank you for agreeing to be in our study. We have just a couple more questions about how to reach you because we want to keep in touch with you.

We will never sell your contact information, share it with anyone, or mail any results of our study to your home.

What is your mailing address? This is required if you want a consent mailed to you

o Address Line 1 _____

o Address Line 2 _____

o City _____

What is your state?

▼ Alabama (1) ... I do not reside in the United States (53)

What is your ZIP code?

Where can we follow you on Social Media?

Twitter handle:
Instagram handle:
Facebook name:

Thank you! Shortly, you will receive an email with your personal link to the first survey. We are excited to have you join our project!